

Application No. 09/710,181  
Amendment "I" dated June 13, 2005  
Reply to Office Action mailed April 5, 2005

### REMARKS

Applicants and Applicants' attorney express appreciation to the Examiner for the courtesies extended during the recent interview held on June 8, 2005. Reconsideration and allowance for the above-identified application are now respectfully requested. Claims 41, 42 and 44-87 are pending, wherein no claims were amended and claims 88-90 were cancelled.

#### I. REMOVAL OF PREVIOUS REJECTIONS

Applicants thank the Examiner for indicating that "Applicant's arguments filed 12/15/04 with respect to the rejection(s) of claim(s) under 35 102(b) and Obviousness-type Double Patenting have been fully considered and are persuasive." Office Action, page 2. In addition, Applicants thank the Examiner for agreeing that examples in application and comparative test "suggest 0.01-2% potassium nitrate yields unexpected results" and that "Examiner is agreement with Applicant's results." Office Action, pages 4 and 5.

#### II. ART REJECTION UNDER 35 U.S.C. § 103

The Office Action rejects 41, 42 and 44-71 under 35 U.S.C. § 103(a) as being unpatentable over Fischer (US 5,985,249). In reply, Applicants note that whereas Fischer '249 has an issue date of November 16, 1999, the present application as originally filed (and now amended) has a filing date of November 12, 1998. That means that Fischer '249 is only citable, if at all, under 35 U.S.C. § 102(e).<sup>1</sup> According to 35 U.S.C. § 103(c)(1), "subject matter developed by another person, which qualifies as prior art only under one or more of subsections (c), (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the claimed invention was made, owned by the same person or subject to an obligation of assignment to the same person." Because Fischer '249 is only citable, if at all, under 35 U.S.C. § 102(e), and because the claimed invention at the time it was made was owned by Ultradent Products, Inc. (the assignee of Fischer), it follows that Fischer '249 cannot be used to reject the claims of the present application under 35 U.S.C. § 103(a).

<sup>1</sup> Applicants do not admit that Fischer '249 is, in fact, prior art since the named inventor is a co-inventor of the subject matter claimed in the present application. Applicants reserve the right to file an affidavit under MPEP § 706.02(k) stating that any "unclaimed invention disclosed in the [Fischer patent] was derived from the inventor(s) of the [present] application and is thus not invention 'by another'".

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Moreover, Applicants submit that the narrow range of potassium nitrate (*i.e.*, about 0.01% to about 2% by weight) is not disclosed in Fischer '249 in any event. That means that the arguments given before and set forth hereinbelow relative to other cited art are believed to apply to Fischer '249 as well. Accordingly, Applicants believe the claims as previously submitted, because they each claim the narrow range of potassium nitrate, are unobvious over Fischer '249.

The same arguments are also applicable to U.S. Patent No. 5,851,512 to Fischer et al. More particularly, Applicants submit that Fischer '512 neither teaches nor suggests the specific narrow range of potassium nitrate (*i.e.*, about 0.01% to about 2% by weight). For this reason, Applicants submit that the claims as previously submitted are neither anticipated by, nor obvious over, Fischer '512.

### **III. OBVIOUSNESS-TYPE DOUBLE PATENTING REJECTIONS**

The Office Action rejects claims 41, 42 and 44-87 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8, 10, 11 and 13-26 of US 6,309,625 (Jensen '625) and claims 1-23 of US 6,306,370 (Jensen '370). During the Examiner Interview, Applicants tentatively offered to file a Terminal Disclaimer relative to Jensen '625, but not to Jensen '370. However, Applicants' representative explicitly based that offer on condition that the Examiner agreed to remove the double patenting rejection relative to Jensen '370. However, the Examiner did not agree to remove the double patenting rejection relative to Jensen '370 during the Examiner Interview but wants time to fully consider Applicants' arguments. Therefore, in order to protect Applicants' right to appeal certain issues and/or to avoid unnecessarily affecting the patent term before all other issues are first resolved, the undersigned attorney will hold in abeyance his offer to file a Terminal Disclaimer relative to Jensen '625 unless and until all other issues are first resolved. Moreover, as will be discussed below, some or all of the grounds for overcoming the double patenting rejection relative to Jensen '370 also apply to Jensen '625. It would make no sense to file a Terminal Disclaimer relative to Jensen '625 if this rejection can be overcome by argument alone.

Applicants first wish to point out that the Examiner agrees and states in the Office Action that claiming a dental bleaching composition that includes a dental bleaching agent in combination with an amount of potassium nitrate within the narrow range of about 0.01% to about 2% by weight is nonobvious over the art of record. As stated in the Office Action:

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Applicants point out in a declaration and a working example that 10.5% and 15% carbamide [peroxide] plus 0.5% potassium nitrate yields unexpected data. Applicant also refers Examiner to non-working examples 3-10 in instant specification, which suggest 0.01-2% potassium nitrate yields unexpected results. Examiner is in agreement with Applicant's results. However, Examiner argues that Applicant does not provide ample results supporting a peroxide amount ranging from 0.5-50%.

Office Action, pp. 4-5 (emphasis added). It was by virtue of claiming this narrow range of potassium nitrate and showing evidence of surprising and unexpected results that previous art rejections were removed (e.g., U.S. 5,256,402 to Prencipe et al.). The result should be no different relative to Jensen '625 and Jensen '370 since neither the specifications nor claims of the Jensen patents teach or suggest the claimed narrow range of potassium nitrate. Nor do the Jensen patents disclose any examples (either actual or prophetic) of bleaching compositions that include an amount of potassium nitrate within the claimed range. As will shown below, the fact that the Jensen patents do not disclose any actual embodiments of the claimed invention, coupled with the fact that the Jensen patents neither disclose nor claim the narrow potassium nitrate range, is dispositive of the double patenting rejections.

Before addressing the Jensen patents and the applicable rules relating to double patenting, Applicants first wish to address the Examiner's concern that "Applicant does not provide ample results supporting a peroxide amount ranging from 0.5-50%", as stated at pages 4 and 5 of the Office Action. Applicants respond by referring to the present application itself, which teaches that the relevant result-effective variable that determines whether tooth sensitivity is reduced is potassium nitrate concentration, not peroxide concentration. See Application, page 8, lines 7-18; page 9, line 24 – page 10, line 7; page 12, lines 7-11 (which relates the degree of desensitization with the potassium nitrate concentration, not the peroxide concentration). Moreover, factors other than peroxide concentration alone can contribute to tooth sensitivity. These include the predisposition of a user to suffer from tooth sensitivity in general or peroxide sensitivity in particular, the time in which the bleaching composition is in contact with a person's teeth, and the duration of the bleaching regime (e.g., 1 week versus several months). Consistent with this, the present application specifically teaches that the preferred narrow concentration range of potassium nitrate (i.e., about 0.01% to about 2%) is most applicable in the case of prolonged contact of the bleaching composition and a person's teeth and/or a bleaching regimen of extended duration. Application, page 13, lines 3-15. Thus, it is the duration of contact between

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a person's teeth and a peroxide dental bleaching agent, not the concentration *per se*, that most contributes to tooth sensitivity. Whereas the Comparative Study tested the effect of using different amounts of potassium nitrate, it utilized a common and customary quantity of dental bleaching agent. It could just as easily have utilized a different quantity of bleaching agent and/or asked participants to bleach their teeth using different time guidelines to achieve some different result. However, such were not the focus of the study.

Because the claims of the present application are directed to inventive dental bleaching compositions, the amount of time a person actually uses an inventive bleaching composition is outside the purview of the claims. Nevertheless, the comparative study clearly demonstrated a reduction in tooth sensitivity resulting from the use of a reduced quantity of potassium nitrate spanning the duration of the study. That demonstrates that the concentration of potassium nitrate, not peroxide, is the relevant result-effective variable with respect to the demonstrated reduction in tooth sensitivity, particularly in the case of an extended bleaching regimen of the type used in the comparative study. If someone were to discover some amount of peroxide, or identify some treatment regimen, that could be shown to reduce or increase tooth or other oral sensitivities, that might form the basis of another patent application. However, it has no relevance to the claims at issue here since the claimed compositions and underlying disclosure, by their very terms, are only concerned with the effect of utilizing specific low amounts of potassium nitrate to offset whatever tooth sensitivity that might be caused by any type or quantity of peroxide bleaching agent, not what amounts of peroxide might themselves cause or not cause tooth sensitivity.

In any event, there is clear symmetry between the amounts of potassium nitrate and peroxide dental bleaching agent required by the claims. The specification teaches that the preferred range of potassium nitrate is "about 0.01% to about 2% by weight". Application, page 13, lines 8-9. The specification also teaches that the preferred range of peroxide bleaching agent is "about 0.5% to about 50% by weight". Application, page 18, lines 20-21. Each independent claim as now amended includes both preferred ranges (*i.e.*, for potassium nitrate and the dental bleaching agent). Accordingly, the claims are clearly limited to what are regarded in the application as the "preferred embodiment" for both potassium nitrate and peroxide bleaching agent. The claims are therefore not unduly broad, either with respect to the potassium nitrate concentration or the bleaching agent concentration. Moreover, the relevant result-effective

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variable in reducing tooth sensitivity is the concentration of potassium nitrate, as shown by the Comparative Study. The effect of varying the concentration of the peroxide bleaching agent is simply not dealt with in the present application, nor was it the subject of the Comparative Study. In short, nothing in the Comparative Study or the application compels limiting the claims to a peroxide concentration other than the preferred range disclosed in the application.

Turning now to the double patenting rejections, Applicants first wish to emphasize that neither the claims nor the specifications of the Jensen patents teach or suggest a dental bleaching composition that includes a peroxide bleaching agent and potassium nitrate in the specific range of "about 0.01% to about 2% by weight". Instead, the Jensen patents disclose preferred, more preferred, and most preferred ranges for potassium nitrate of "about 0.1% to about 50% by weight", "about 1% to about 25% by weight", and "about 3% to about 10% by weight", respectively. Jensen '625, col. 6, lines 43-49; Jensen '370, col. 6, lines 53-59. Although there is some overlap between the narrow range of the present invention and the preferred and more preferred ranges of the Jensen patents, such overlap is very slight. More particularly, the narrow range of about 0.01-2% only overlaps about 4% of the values contained within the preferred and most preferred ranges (*i.e.*, about 2% of 50% and about 1% of 25% both equal about 4%). That means that about 96% of the possible concentration values for potassium nitrate taught as being "preferred" and "more preferred" in the Jensen patents fall *outside* the narrow range of the present invention. There would have been no way for one of skill in the art, based on the broad ranges taught in the Jensen patents, to identify the narrow range of values that was later discovered to provide the surprising and unexpected results shown by the Comparative Study. Moreover, the fact that the "most preferred" range taught in the Jensen patents (*i.e.*, about 3-10%) lies *completely outside* the narrow range of the present invention (*i.e.*, about 0.01-2%) would have lead one of skill in the art away from the inventive narrow range of the present application rather than toward it. Similarly, every working example disclosed in the Jensen patents that includes both potassium nitrate and a bleaching agent includes potassium nitrate in an amount that is *outside* the inventive narrow range, thus further leading away from the claimed inventive compositions of the present application.

As discussed during the Examiner Interview, the proper inquiry when determining whether there is double patenting is to look mainly at the claims. Thus, the claims in the present application should be compared with the *claims* of the Jensen patents to determine whether the

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present application seeks to claim an obvious variation of any invention that is *claimed* in the Jensen patents. As discussed above, the Comparative Study shows that including potassium nitrate in a concentration of about 0.01% to about 2% by weight in a bleaching composition yields surprising and unexpected results compared to amounts of potassium nitrate outside this range. The *claims* of the Jensen patents do not claim the specific narrow range that yields the surprising and unexpected results. Nor would the specific narrow range showing the proven unexpected results be *obvious* over the ranges found within the *claims* of the Jensen patents (*i.e.*, about 0.1%-50%, about 1-25%, and/or about 3-10%). In short, one of skill in the art, when viewing the ranges set forth in the Jensen patents, would not have been motivated to select the specific narrow range now claimed.

In addition to the claims, MPEP § 804 also states that the patent disclosure may also be consulted, *e.g.*, to find out what the claims mean:

When considering whether the invention defined in a claim of an application is an obvious variation of the invention defined in the claim of a patent, the disclosure of the patent may not be used as prior art. This does not mean that one is precluded from all use of the patent disclosure.

The specification can always be used as a dictionary to learn the meaning of a term in the patent claim. *In re Boylan*, 392 F.2d 1017, 157 USPQ 370 (CCPA 1968). Further, those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent. *In re Vogel*, 422 F.2d 438, 441-42, 164 USPQ 619, 622 (CCPA 1970). The court in *Vogel* recognized "that it is most difficult, if not meaningless, to try to say what is or is not an obvious variation of a claim," but that one can judge whether or not the invention claimed in an application is an obvious variation of an embodiment disclosed in the patent which provides support for the patent claim. According to the court, one must first "determine how much of the patent disclosure pertains to the invention claimed in the patent" because only "[t]his portion of the specification supports the patent claims and may be considered." The court pointed out that "this use of the disclosure is not in contravention of the cases forbidding its use as prior art, nor is it applying the patent as a reference under 35 U.S.C. 103, since only the disclosure of the invention claimed in the patent may be examined."

MPEP § 804 (emphasis added). In view of MPEP § 804, it is clear that the specifications of the Jensen patents may be "examined and considered" but "only the disclosure of the invention claimed in the patent may be examined".

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Turning to the issue at hand, the relevant inquiry concerns what portions of the disclosure in the Jensen patents supports the claims at issue. The issue at hand relates to whether the inventive narrow range of about 0.01-2% potassium nitrate would have been obvious in light of claimed amounts of potassium nitrate in the Jensen patents. The PTO may therefore consult the disclosures of the Jensen patents relative to the concentration of potassium nitrate. As discussed above, the Jensen patents disclose ranges that are so different from the claimed narrow range at issue that one of skill in the art would not have been motivated to select the claimed narrow range of "about 0.01% to about 2% by weight" of potassium nitrate in a dental bleaching composition. Moreover, none of the examples of the Jensen patents, which also provide support for the Jensen patent claims, disclose a dental bleaching composition that includes potassium nitrate within the inventive narrow range. In view of this, the claims of the Jensen patents, especially when viewed in light of their underlying disclosures, neither teach nor suggest the claimed narrow range.

In short, Applicants submit that the claims of the present application define a narrow class of dental bleaching compositions that possess surprisingly and unexpectedly reduced tooth sensitivity which are neither taught nor suggested by either the claims or the disclosures of the Jensen patents. Because this is true for Jensen '625, as well as Jensen '370, it is unnecessary for Applicants to file a terminal disclaimer relative to either patent. Accordingly, Applicants respectfully request reconsideration and withdrawal of all double patenting rejections in view of the remarks set forth herein.

### III. CONCLUSION

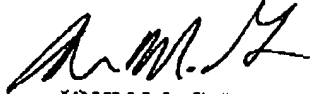
In view of the foregoing, Applicants submit that the claims as amended are in allowable condition. In the event that the Examiner finds any remaining impediment to a prompt allowance of this application which may be clarified through a telephone interview or that may

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be overcome by examiner amendment, the Examiner is requested to contact the undersigned attorney.

Dated this 6<sup>th</sup> day of June 2005.

Respectfully submitted,



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